Remarks

Claims 1, 19 and 23 have been amended to define metabolites of formula I by structure. The substituents for "A", "B" and "M" have been amended to include oxides and the general reference to metabolites has been deleted.

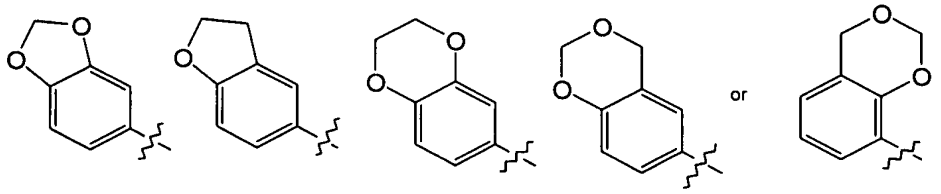
Restriction Requirement

Applicants repeat their request that claims 8-18, drawn to a method of treating and preventing various diseases using products of Formula I, be rejoined once allowable subject matter within Group 1 has been identified.

Rejection Under 35 USC§112, first paragraph

Applicants traverse the rejection of claims 1-7 and 19-25 under 35 USC §112, first paragraph, based on the allegation that the specification does not provide an enabling disclosure for using all of the compounds of claim 1.

The specification has been found to be enabling for compounds where A is phenyl, naphthyl, benzodiox [—yl] , indazolyl, quinolinyl or a group of one of the formulae:



and where B is phenyl and L is "O".

Therefore, the rejection does not apply to claims 4 and 6, which already define A , B and L in this manner.

Not one shred of evidence has been presented which remotely suggests the specification does not enable the full scope of compounds of formula I. In the absence of such evidence, the rejection is deficient under controlling case law. The burden is upon the

Patent and Trademark Office to provide evidence shedding doubt that the invention can not be made and used as stated; see for example, *In re Marzocchi*, 439, F. 2d 220, 169 USPQ 367 (CCPA 1971).

The compounds which are allegedly not enabled include those where B of formula I is pyridyl or naphthyl. No evidence has been presented to suggest that such compounds are not active or that the specification does not enable the use of these compounds in treating a disease. Instead a conclusions is made based on the alleged unpredictable nature of the art, generally. In fact, there are teachings in the art that aryl ureas having a phenyl moiety for "B" and those having a naphthyl moiety for "B" are both active. See, for example, WO 00/43384, directed to inflammatory agents There are also teachings in the art that aryl ureas having a pyridyl moiety for "B" and those having a phenyl moiety for "B" are both active. See, for example, WO 99/32106.

Compounds where "L" is other than oxygen are also said not to be enabled by the disclosure, although no evidence supporting this conclusion has been presented. Both WO 00/43384 and WO 99/32106 teach variations in the moiety "L," consistent with those recited in claim 1 herein. Based on these teachings, there is clearly no basis to question the activity of compounds where L is not oxygen.

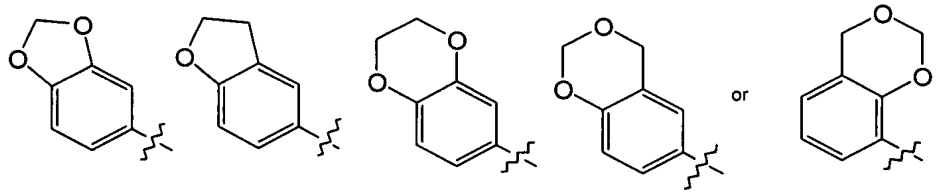
Clearly claims 2-6 and claims 19-25 meet the requirements of 35 USC 112 , first paragraph, in view of the teachings within the specification and the prior art.

Compounds of formula I where "A " is mono- or bi-cyclic heteroaryl are also said not to be enabled by the specification. The definition for "mono- and bi-cyclic heteroaryl" groups is provided on page 17 , line 24 through page 18, line 11, of the specification, portions of which are repeated below.

Monocyclic heteroaryl means an aromatic monocyclic rings having 5 to 6 ring atoms, at least one of which is a hetero atom selected from N, O and S, the remaining atoms being carbon....

Bicyclic heteroaryl means fused bicyclic moieties where one of the rings is chosen from the monocyclic heteroaryl rings described above and the second ring is either benzene or another monocyclic heteroaryl ring described above.

These definitions prescribe moieties of a size which conform to the phenyl groups and naphthyl groups illustrated in the examples of the application and also conform to the size and composition of the quinolin groups and the those of the formulae:



Based on the similarities in size and composition to the moieties within the compounds illustrated and those of the monocyclic and bi-cyclic heteroaryl compounds, there is a reasonable basis to assume these compounds will share the same pharmacological activity as those illustrated in the specification. No evidence has been presented to the contrary. Therefore, claims 1 and 7 satisfy the requirements of the statute.

The enablement requirement, "is satisfied if, given what they [, those of ordinary skill in the art,] already know, the specification teaches those in the art enough that they can make and use the claimed invention without 'undue experimentation." See *Amgen v Hoechst Marion Roussel*, 314 F.2d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003). Applicants clearly provide sufficient guidance to make and use the compounds of this application. The synthesis of the compounds is described generally on pages 22-26 and in the examples. Methods for preparing pharmaceutical compositions with these compounds and methods for administering compounds in the treatment of patients are provided on pages 27-38. Dosages are provided on page 41. To the extent the disclosure does not provide specific dosages, it would at most involve routine experimentation, if any at all, for one skilled in the art to treat any one of the recited diseases with the compounds of this invention. Furthermore, it would

not be undue experimentation to test these compounds for the activity disclosed in the specification. Such testing is routine, performed on a day to day basis by those skilled in the art .

For the reasons indicated above, Applicants maintain that they have provided more than adequate guidance and examples to enable the claimed invention and submit all claims meet the requirements of 35 U.S.C. §112, first and second paragraphs.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

Richard J. Traverso, Reg. No. 30,595
Attorney/Agent for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 812 -5310
Facsimile: (703) 243-6410
Attorney Docket No.: BAYER-0043
Date: June 29, 2007